UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Region VIII

Draft Comment Response
Technical Memorandum No. 8 - Toxicity Constants
Operable Unit 1
October 1992

GENERAL COMMENTS:

The purpose of the Technical Memorandum No. 8 is to describe the selection process which will be used in the baseline risk assessment (BRA) to identify contaminants of concern (COCs) for contaminated media in operable unit (OU) 1. This is a critical phase of the remedial investigation because the selected COCs are used exclusively to quantify human health risks in the BRA. Contaminants eliminated during this stage of the analysis will be disregarded for further consideration in the BRA. For this reason, a thorough review of contaminant concentrations, locations, and statistical analysis is warranted.

The veracity of the document could not be confirmed due to the lack of data and descriptive methodology. Summary tables of chemical concentrations and statistical analysis are well presented, but are insufficient to ascertain whether the selected COCs definitively represent the entire inventory of hazardous chemicals for OU 1.

The decision to limit evaluation of ground water analytes to volatiles and semi-volatiles does not present a complete analysis for the baseline risk assessment. Due to the fact that the potential for direct exposure to ground water (ingestion and dermal) has not been completely eliminated, it is necessary to consider all analytes that could be associated with this pathway in the process of identifying contaminants. This would be best accomplished by developing a separate list of contaminants specific to direct ground water exposure. By compiling two separate lists for the different ground water exposure scenarios, any differences in identified contaminants will be readily apparent and more easily managed.

For completeness, it is necessary to evaluate analytical data collected from subsurface soils in addition to the surface soil data that was evaluated in this technical memorandum. This need not take the form of two separate lists as specified above for ground water contaminants. EPA's concern is that all contaminants detected in subsurface soils must be considered in this process and that this must be demonstrated in the BRA.

Also of great concern is the methodology used for eliminating chemicals which represent < 1 % of the total risk. The process of simply multiplying the water or soil concentration by the slope factor or reference dose is not appropriate and misleading. Since slope factors and reference doses are based on the probability of an effect given a specified intake rate and exposure time, the comparison should be made on the same basis. In other words, a chronic daily intake should be calculated for each chemical using its

concentration in soil or water and the default exposure equations provided in RAGS, Part A. For a carcinogen, the chronic daily intake should be multiplied by the slope factor to determine the risk. If that risk is less than say 10E-08, the chemical can be excluded as a COC. For a non-carcinogen, the chronic daily intake is divided by the reference dose. If the resulting Hazard Quotient is less than 0.01, the chemical can be excluded as a COC.

With the procedures outlined on pages 2-18 through 2-23, a number of chemicals which could pose an adverse risk are eliminated. For example, on page 2-19, both chloroform and methylene chloride are calculated to contribute <1% of total risk and, according to the text on page 2-18, are eliminated as COCs. Both of these chemicals are carcinogenic and have slope factors in EPA's IRIS Database. However, these slope factors were not included in the table. Based on these slope factors, acceptable health based concentrations in drinking water for chloroform and methylene chloride are 2.2 ug/l and 8/4 ug/l respectively, whereas the maximum concentrations for these compounds listed on page 2-19 are actually 170 ug/l and 620 ug/l. These two chemicals are added back into the COC list at the end of the tech memo because of other factors, but the fact that they were even eliminated emphasizes the major flaws in this screening procedure. Other chemicals which were eliminated by this screen, but should have been kept in include toluene, benzo[a]pyrene, benzo[b]fluoranthene, benzo[k]fluoranthene, and AROCLOR 1254. Again, some of these chemicals were added back in for various arbitrary reasons at the end, but the point is, they should never have been eliminated.

The first step of the screening procedure on page 2-4 recommends that all essential elements be eliminated from further consideration as contaminants of concern. Page 2-5, paragraph 3, states that this is according to the direction of EPA Region 8. This is incorrect. At the meeting referenced at the bottom of page 2-5, EPA cautioned against using this criteria since it would also exclude selenium, chromium, zinc, and perhaps arsenic. This criteria should be modified to reflect the entire scope of the guidance in RAGS, Part A, page 5-23, "Chemicals that are (1) essential human nutrients, (2) present at low concentrations (i.e., only slightly elevated above naturally occurring levels), and (3) toxic only at very high doses (i.e., much higher than those that could be associated with contact at the site) need not be considered further in the quantitative risk assessment."

Response: Summary statistics of contaminant concentrations were provided with the document. A complete ground water data set was provided on disk at an earlier date (August 1992), along with on-site contractor assistance at the EPA Region VIII office. Other data are available upon request.

It is DOEs position that the French drain will be considered to be part of the site and risks attributable to direct ingestion of ground water will not be quantitatively assessed (see comment response to Technical Memorandum No. 7). Consequently, the screening process was applied only to volatile and semi-volatile compounds relevant to the vadose zone vapors for the soil-gas pathway. Metals and radionuclides of interest at

OU1 do not volatilize, and inclusion would interfere with the toxicity screen.

Contaminant concentrations were higher in surface soil data than in sub-surface soil data, therefore, surface soil data was used to identify COCs.

The screening process used was applied according to guidance in RAGS Section 5.9.5. DOE has discussed alternative methods for the screening process and received input from EPA/CDH on numerous occasions, including several interagency meetings (late summer 1991, November 21, 1991, December 11, 1992, July 15, 1992). EPA has generally agreed that screening COCs is germane, and it is practiced by the agency. After each meeting, EPA/CDH input has been incorporated. In fact, it was at EPA's suggestion that the risk-based screening step was replaced with the RAGS toxicity screen, and the essential nutrient screening step was moved to the front portion of the screening process. After it was issued, a teleconference call was held on September 18, 1992. Several concerns were discussed, and the message from EPA at the end of the call was that there were "no show-stoppers."

RAGS suggests using a 99 percent cut-off unless expected risks are high, in which case 99.9 percent is suggested. RAGS does not define expected "high" risks, but it is reasonable to assume that it is well above the NCP acceptable risk range (10^{-6} to 10^{-4}). Preliminary risk estimates indicated that the site-wide RME risk would be within the NCP risk range. In addition, the risk factors estimated using the method in RAGS 5.9.5 do not consider transport and fate and therefore "have no meaning outside the context of the screening procedure". Without reason to expect high risks, the suggested cut-off value of 99 percent was used.

SPECIFIC COMMENTS:

1. *Page 2-2. Fourth Paragraph. Sample dilutions and matrix effects responsible for variations between sample quantitation limits (SQLs), are a necessary component of chemical analyses of environmental contaminants. The results from high SQLs are as valid as those from lower SQLs or "the most commonly observed detection limit." However, bias is introduced into the selection of COCs when high SQLs are arbitrarily eliminated from the data set. Because there is an equal probability that the contaminant may not be present in the sample or may be present at a level just below the SQL, Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual, Part A (RAGS) (EPA, 1989a) presents a compromise. One-half of the SQL should serve as the proxy value for computing the mean, standard deviation, and upper 95 percent confidence limit concentrations for nondetected chemicals. The only exception to this rule is when the calculated exposure concentration exceeds the maximum detected concentration for a particular sample set (EPA, 1989a). If high SQLs are eliminated from the analysis, the frequency of detection is greatly affected. Chemicals that could otherwise be eliminated from consideration based on a frequency of detection of 5 percent of less can be unnecessarily retained and carried through the quantitative risk assessment. Retaining these infrequently detected chemicals could ultimately result in the elimination of high-priority hazardous chemicals from the list of COCs during the application of the toxicity-concentration screen. Therefore, to ensure a complete list of COCs, data should be analyzed according to RAGS and not arbitrarily eliminated from the database.*

   Rationale: Data should be analyzed according to RAGS (EPA, 1989a), and not arbitrarily eliminated from the data base. Inconsistent elimination of data could result in an inaccurate list of COCs.

   Response: The approach used was consistent with RAGS Section 5.3.2 for the elimination of unusually high SQLs. In addition, the approach used was consistent with suggestions from the EPA Region VIII statistician for the treatment of background geochemical data. As stated in Technical Memorandum No. 8, the detection frequency screening was conducted before elimination of the high SQLs, thus avoiding bias of the toxicity screen with infrequently detected chemicals.

2. *Page 2-13. Section 2.2.3. The methodology used to screen for hot spots was not adequately described. From the brief discussion presented, however, the spatial distribution of contaminants across OU1 does not appear to have been taken into consideration and the identification of hot spots appears to be based solely on the inspection of tabulated data. In addition, the analysis should be conducted with reference to sample locations.*

   Rationale: Tabulated data and spatial information on the location of elevated concentrations should both be used to identify hot spots.

Response: The locations of the hot spots were presented in Appendix A of Technical Memorandum No. 8. Thus, both tabulated data and location were used to identify hot spots. Hot spots were qualitatively evaluated using the criteria of spatial localization and elevated concentration. The locations of the hot spots were presented in Appendix A of Technical Memorandum No. 8. The only contaminants that met both criteria were VOCs, for example, in IHSS 119.1. VOC concentrations were elevated by approximately two orders of magnitude.

3. *Page 2-13, Section 2.2.3. Simply comparing elevated concentrations to the central tendency (the mean or median) concentration is insufficient for identifying hot spots, particularly for soil contaminants. A more conventional and rigorous approach uses the difference between the highest and lowest detected concentration. This is because the difference between the central indicator and the highest detected value will be small when the chemical concentrations from all samples are at the same elevated levels. The mathematical basis for this approach is that the two variables are not independent because the mean concentration depends on the individual concentrations. Pooling the elevated concentrations will result in a weighted average biased in the direction of high concentrations. The difference between individual elevated concentrations and the mean, therefore, will be relatively small. No bias is introduced when the maximum and minimum concentrations are compared because the variables are independent.*

Also, as mentioned in comment number 2, a correlation between the spatial distribution and elevated contaminant concentrations is a necessary component of any hot spot analysis.

Rationale: The range of contaminant concentrations should be used to screen for hot spots in OU1.

Response: The method used was presented in the meeting of July 15, 1992 and EPA feedback at the time was positive. DOE asked for input in defining hot spots, and EPA suggested that the definition of hot spot could be found in Gilbert (1987). However, that reference only offers methods for finding a hot spot once it has been defined. In the absence of any further suggestions, the method presented in the meeting was used.

Hot spots were qualitatively evaluated using the criteria of spatial localization and elevated concentration. The locations of the hot spots were presented in Appendix A of Technical Memorandum No. 8.

4. *Page 2-13, Section 2.2.4. Background data, such as the mean, standard deviation, range, and upper 95 percent confidence limit, are not presented in the document. Lacking this information, it could not be concluded that site-related contaminants are equal to or less than background concentrations. This information is an integral part of the selection of COCs because the elimination of inorganic contaminants is based on this criterion. This information should be tabulated along with site-specific data.*

Rationale: Background information used to eliminate chemicals from the list of COCs must be included with site-specific information.

Response: The background data was inadvertently omitted the background data during reproduction. It has been included in the October 1992 Draft of the PHE. Upon request, DOE will provide the data on computer disk, just as a complete set of ground water data was provided immediately on computer disks along with on-site contractor assistance at the EPA Region VIII office.

5. *Page 2-17, Last Paragraph. Why are published sources of background data being used here for comparison with site data? Any use of published data must be justified and must accurately represent actual site background conditions. Sufficient information must be presented to allow a judgement to be made as to the applicability of published sources to the naturally occurring site-specific conditions.*

Rationale: Use of published sources for background data must be justified and shown to represent actual site conditions at Rocky Flats.

Response: During several interagency meetings (late summer 1991, November 21, 1991, December 11, 1992, July 15, 1992), the use of site specific and published background values was discussed. Preference was given to the site specific data, however, as a reality check, published data was consulted for chemicals and radionuclides that are known to be ubiquitous. If common rock-forming metals (copper, molybdenum, vanadium, cesium, and zinc) had concentrations in agreement with published U.S. or world background values, then the site was not considered to be the source. Retention of chemicals or radionuclides attributable to background interferes with the toxicity screen and could result in COCs not representative of the site.

6. *Page 2-13, Section 2.2.4. The selection of statistical tests to compare background and site-specific chemical information appears to be flawed and should be reevaluated. The fundamental assumption that the data are nonparametric rather than parametric is incorrect since the sample data are continuous and random and not restricted to discreet "fixed" numerical values. As such, it is not appropriate to sue nonparametric statistical analysis such as the Mann-Whitney test. A commonly used decision tree for selecting appropriate statistical tests has been included as a reference.*

Rationale: The statistical test employed should reflect the probability density function of the data.

Response: Parametric tests (the F test and Bartlett's test) were used where applicable. Where distributions were non-parametric, the non-parametric Mann-Whitney U test was used.

7. *Page 2-14, Second Paragraph. It is incorrectly stated that Bartlett's Test and the F-test can be used to determine the statistical difference between mean concentrations. The singular utility of these tests is to determine heterogeneity or homogeneity of sample variances. Subsequently, the result of these tests are used only to choose the appropriate statistical test for the null hypothesis, such as Student's t- or Cochran's t-test. A statistical difference between mean concentrations can be determined only after applying the null hypothesis with these tests. Thus, while Bartlett's- and the F-test are important to the overall strategy of statistical tests, they are inappropriate for testing the null hypothesis used to determine differences between mean concentrations.*

Rationale: Tests of variance cannot be used to determine statistical differences between means.

Response: These tests were clarified during the September 18, 1992 conference call. The F test uses analysis of variance (ANOVA) to test the hypothesis that the means are equal. The variance between groups is compared to variance within the groups, consequently the variances within the groups needs to be homogeneous. Bartlett's test was used to test the hypothesis that the variances within the groups were homogenous, or equal (Walpole 1978).

8. *Page 2-8, Table 2-2a. As presented in the summary statistics in the appendices, the maximum concentration for aluminum in soil is 270,000 parts per billion (ppb). The minimum and maximum values appear to be transposed in Table 2-2a and should be corrected.*

Rationale: There appear to be inconsistencies between summary statistics and tabulated data.

Response: This typographical error has been noted and will be addressed in the Final PHE.

9. *Page 2-15, Table 2-3. This table is confusing and should be further clarified. It is not clear what "yes" and "no" refer to in columns. Based on the limited description, however, it appears that beryllium and nickel should have been selected as COCs. It is indicated on the table that they are present onsite at concentrations higher than background.*

Rationale: The table is confusing in its current form and should be modified.

Response: Comment noted. With regard to beryllium and nickel, the "No" response for the mean rank sum comparison indicates that the site population was greater than background, however the "Yes" in the adjacent column indicates that the chemical was eliminated because the difference was not statistically significant. Beryllium and nickel were correctly eliminated from the potential COC list.

10. *Page 2-19, Table 2-4. The source of toxicity constants appear to be in error for several chemicals. The reference dose for some chemicals, such as trichlorofluoromethane, are either incorrect or has been derived using equations not presented in the table or text. Methods used to derive individual toxicity constants that are different from EPA methodology, and rationale, justifying their use, should be provided. In addition, the risk factor for 1,1-dichloroethane should be 350.*

Rationale: Sources of toxicity information should be corrected and derivations that deviate from EPA values presented. Risk factors should be recalculated.

Response: The reviewer is correct that all of the sources for the individual toxicity constants are not correct. The RfDs for acetone, carbon tetrachloride, chloroform, and tetrachlororethene are from IRIS. All other RfDs are from the *Health Effects Assessment Summary Tables Annual FY-1991* (HEAST 1991). The inhalation RfD for trichlorofluoromethane is reported in HEAST (1991). The inhalation RfDs for methylene chloride, toluene, and 1,1,1-trichloro-1,2,2-trifluoroethane were derived using the references concentrations (RfCs) reported in HEAST 1991 according to the following equation specified in HEAST (1991):

$$\text{RfD (mg/kg-day)} = \frac{\text{RfC (mg/m}^3\text{)} \times (20\ \text{m}^3\text{/day})}{70\ \text{kg}}$$

where 20 m^3/day and 70 kg are the standard default inhalation rate and body weights for adults. The typographical error is noted, but the correct risk factor for 1,1-dichloroethane of 350 will still result in elimination by the toxicity screen.

11. *Page 2-19, Table 2-4. Bis(2-ethylhexyl)phthalate is a class B2 carcinogen with a carcinogenic slope factor of 1.4E-2 mg/kg-day but is presented as a noncarcinogen in Table 2-4. The toxicity values for 1,1,1-trichloroethane, 1,1-dichloroethane, and cis-1,2-dichloroethene are currently under consideration in EPA's Integrated Risk Information System (IRIS), but reference doses (RfDs), from some unknown source are presented in the table. The methodology used to derive the values for these chemicals should be presented.*

Rationale: The classification of chemicals in Table 2-4 should be reexamined and methodology used to derive toxicity constants presented.

Response: Since HEAST (1991) lists both a RfD and a slope factor for bis(2-ethylhexyl)phthalate, it is correct to treat it as both a carcinogen and a noncarcinogen. Thus, the inclusion of bis(2-ethylhexyl)phthalate in Table 2-4 is correct.

We agree EPA is currently evaluating the RfDs for 1,1,1-trichloroethane, 1,1-dichloroethane, and cis-1,2-dichloroethene in IRIS. We spoke with EPA Region VIII Toxicologist Chris Weis, who advised us that it is appropriate to use the values listed in HEAST (either the Annual FY-1991 manual or the March 1992 update) if values were not listed in IRIS. The RfDs listed for 1,1,1-trichloroethane, 1,1-dichloroethane, and cis-1,2-dichloroethene (0.09 mg/kg-day, 0.1 mg/kg-day, and 0.01 mg/kg-day, respectively) are listed in HEAST (1991).

12. *Page 2-20. Table 2-5. The inhalation slope values for compounds in this table are not listed in IRIS. Trichloroethene and tetrachloroethene are classified in IRIS as having no data to determine the potential carcinogenicity but risk factors are included in this table. The acronym "ND" should also be footnoted since the meaning is unclear.*

The slope factors multiplied by the concentrations do not equal the risk factors listed. If a conversion factor is being used, it should be referenced and explained.

The source of the toxicity constant for 1,1,2-trichloroethane is listed as "none." The derivation of this constant should be explained.

Rationale: Sources of information, important assumptions, and conversion factors should be presented in the text.

Response: The inhalation slope factors listed in Table 2-4 for chloroform, methylene chloride, 1,1-dichloroethene, and carbon tetrachloride were derived from the inhalation unit risk values of $2.3x10^{-5}$ $\mu g/m^3$, $4.7x10^{-7}$ $\mu g/m^3$, $5.0x10^{-5}$ $\mu g/m^3$, and $1.5x10^{-5}$ $\mu g/m^3$, respectively, listed in IRIS. Since the document was issued the inhalation slope factor listed in Table 2-5 for trichloroethene of $1.7x10^{-2}$ $(mg/kg\text{-}day)^{-1}$ has been withdrawn from IRIS. The oral slope factor of $1.1x10^{-2}$ $(mg/kg\text{-}day)^{-1}$ will be substituted for trichloroethene in Table 2-5. The inhalation slope factor of $5.7x10^{-2}$ $(mg/kg\text{-}day)^{-1}$ listed in Table 2-5 for 1,1,2-trichloroethane is listed in HEAST (1991). The inhalation slope factor of $1.8x10^{-3}$ $(mg/kg\text{-}day)^{-1}$ listed in Table 2-5 for tetrachloroethene is derived from the unit risk concentration of $5.2x10^{-7}$ $\mu g/m^3$ listed in HEAST (1991). Again EPA Region VIII Toxicologist Chris Weis advised us that it was appropriate to use the values listed in HEAST (either the Annual FY-1991 manual or the March 1992 update) if values were not listed in IRIS. The acronym ND means that a cancer slope factor for compound has not yet been determined.

13. *Page 2-22. Table 2-7. The source of the toxicity constants for radiological contaminants should be the Health Effects Summary Tables (HEAST), not IRIS.*

Rationale: Sources of information should be referenced correctly.

Response: The correct source of the cancer slope factors for radiological chemicals is HEAST (1992).

14. *Page 2-22, Table 2-8. The slope factor for AROCLOR-1254 is found in IRIS, not HEAST. Similarly, the carcinogenic slope factor for benzo(a)pyrene is 5.8, not 6.1 mg/kg-day. Although a few EPA regions have applied the Toxicity Equivalency Factor (TEF) approach for PAH's, this is not approved national policy. For this reason, risk estimates with PAH's should include calculations using the standard EPA method of equating all PAH's equivalent to benzo(a)pyrene in toxicity, as well as calculations based on the TEF approach.*

The TEF for ideno(1,2,3-d,d)pyrene is 0.1 which, when multiplied by the slope factor of benzo(a)pyrene, results in a slope factor of 0.58.

Response: The correct reference for the slope factor for AROCLOR is IRIS. This change will be made. At the time that this memo was prepared, the oral slope factor listed in IRIS for BaP was 5.8 $(mg/kg\text{-}day)^{-1}$. Since the inhalation slope factor of 6.1 $(mg/kg\text{-}day)^{-1}$ listed in HEAST (1991) was bigger, we conservatively used the higher value to calculate the risk factor for BaP, since inhalation and ingestion of soil were potential exposure pathways for this site.

Risks associated with human exposure to polycyclic aromatic hydrocarbons will be calculated using the TEF approach approved by Region IV and endorsed by Region VIII (see Attachment).